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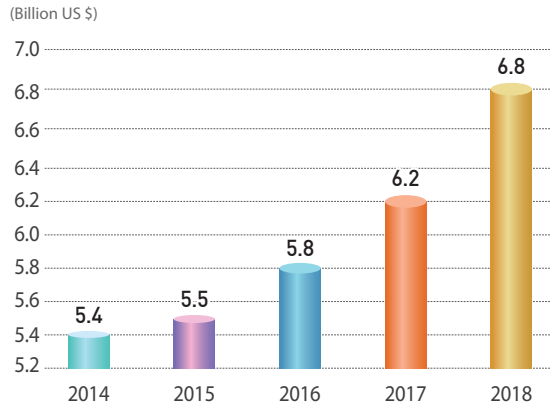
Your VISION,
Our FUTURE
Korean Medical Device

Ministry of Food and
Drug Safety

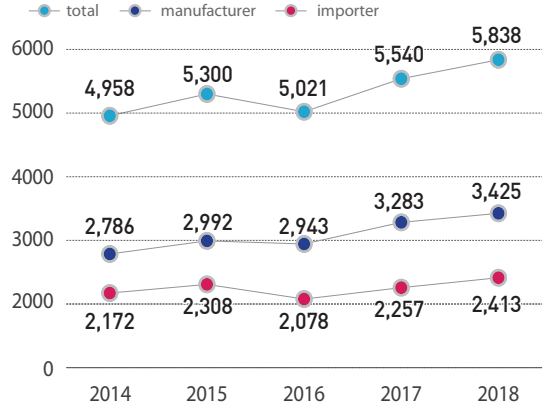
01. Passion for Growth Excellence

Korea's medical device market ranks as the ninth largest in the world at an estimated 6.8 billion USD in 2018, showing continuous grow with 8.1% annual increase.

Korean MD Market Size



Korean MD Companies



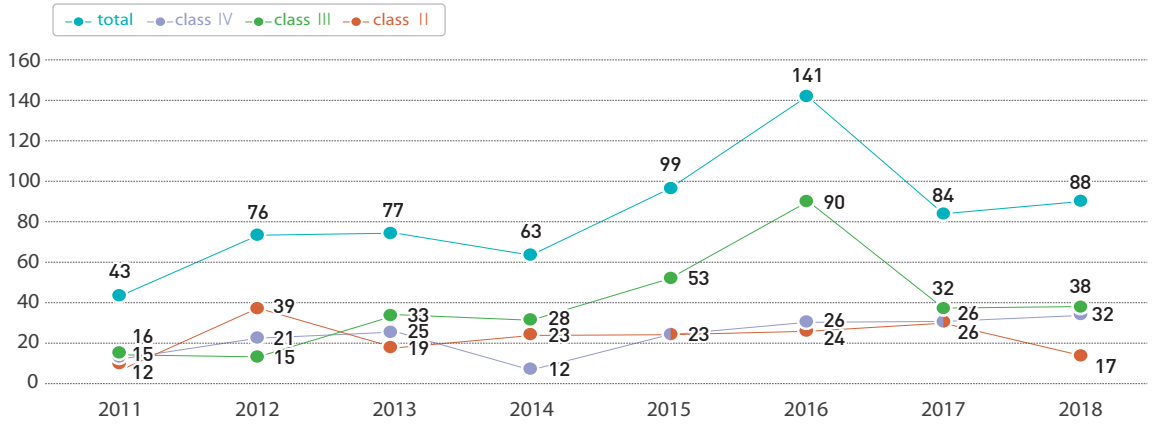
As producers of world class technology, Korean medical device manufactures are attempting to export to the global medical devices market whose safety and effectiveness have been proven by Ministry of Food and Drug Safety (MFDS).

Major Exports of Korean Medical Devices in 2018

Ranking	Top10 Exports
1	Ultrasound Imaging system
2	Biomaterial Graft/Prosthesis
3	Soft Contact Lens
4	Dental Implant
5	IVD Reagents for Self-testing
6	IVD Reagents for Infectious Disease
7	Dental X-ray System
8	Medical Image, Analog to Digital Transform, DR, CR
9	IVD Reagents for HIV, HBV, HCV, HTLV
10	Dental Implant Supersturcture

Korea has become a clinical trial powerhouse for various innovative medical devices with the accelerated clinical trial approval system and ISO 14155 compliance.

Clincal Trial Approvals



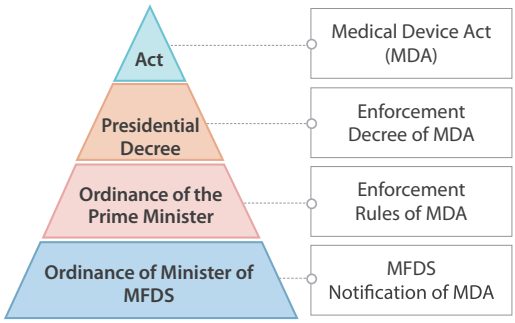
There are a total of 166 clinical trial centers designated by MFDS, providing diverse and robust environments for clinical trials.

Clinical Trial Centers

02. Internationally Aligned Medical Device Regulatory System

Korean regulatory systems, harmonized with the global regulations, allow MFDS to manage the medical devices more effectively.

Medical Device Regulations



Overall MD Regulatory System and its Operation

- **Developed regulatory system by legislating Medical Device Act in 2003**
- **Established risk-based Medical Device Classifications in 2003**
  –I~IV Classes based on GHTF/IMDRF principles
  –Designation of 2,239 items
- **Introduced QMS for medical device in 2004**
  –Harmonized with ISO 13485
- **Established Clinical trial for medical devices in 2005**
  –Harmonized with ISO 14155

MFDS has an efficient and well-balanced system to manage the overall lifecycle of medical devices

Overall Medical Device Regulations

Tasks

Pre-Market	QMS Conformity	Conformity Assessment	Manufacturing (Class II to IV) Importing (Class II to IV)
	Business License	Approval of business license for manufacturing and importing	
	Clinical Trial	Approval for Clinical Trial Plan (If required)	
	Marketing Authorization – Notification (class I)	Notifications of Item (immediately notified at the submission of application) ※ Exemption of QMS inspection	
	Marketing Authorization – Certification - Approval (Class II to IV)	Certification	Class II
		Approval	Class III & IV
Distribution	Selling-Renting-Repairing	Listing for Selling, Renting & Repairing Businesses	
Post-Market	Post-Market Safety Management	Re-Certification of QMS conformity	
		Management of Labeling and Advertising	
		Adverse Event Reporting	
		Recall	
		Tracking of High Risk Medical Devices	
		Enforcement Actions (Fines/Restitutions, etc)	

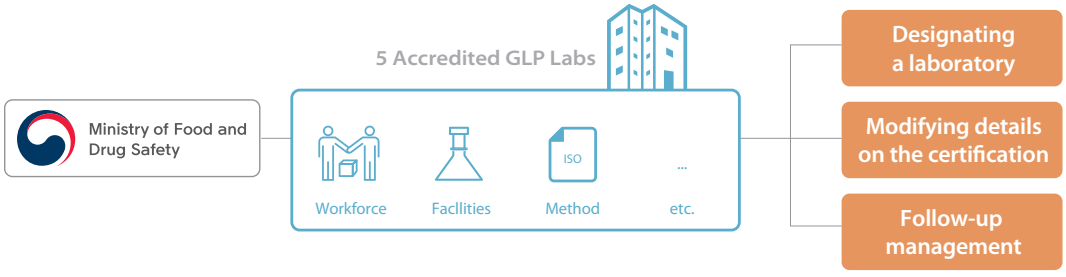
For Class 4 devices with higher risks, UDI system will reinforce the whole management of medical devices

- UDI System allows us to manage UDI information, related information, information of the manufacturer and importer
- The starting date of UDI in each class

	Class 4 (high risk)	Class 3 (serious risk)	Class 2 (potential risk)	Class 1 (lower risk)
Placing UDI	July, 2019	July, 2020	July, 2021	July, 2022

Mandatory GLP System for Medical Devices

- To enhance confidence in biological safety testing of medical devices contacting or inserted into human body
- To reduce time and cost for pre-market approval by mutually accepting GLP study data among OECD-recognized MAD countries when exporting to the other countries



03. Strategic Operation based on Expertise & Efficacy

With a systematic organization struture, MFDS is strategically operated for an effective medical device management

Medical Device Safety Bureau	Medical Device Evaluation & Research Department	6 Regional Branches
Divisions	**Divisions**	**Divisions**
▸ Medical Device Policy Division ▸ Medical Device Management Division ▸ Medical Device Safety Evaluation Division	▸ High-tech Medical Devices Division ▸ Cardiovascular Devices Division ▸ Orthopedic & Restorative Devices Division ▸ Dental & Gastroenterology Devices Division ▸ In Vitro Diagnostic Device Division ▸ Medical Device Research Division	▸ Seoul Regional Office of MFDS ▸ Busan Regional Office of MFDS ▸ Gyeongin Regional Office of MFDS ▸ Daegu Regional Office of MFDS ▸ Gwangju Regional Office of MFDS ▸ Daejeon Regional Office of MFDS
Main Tasks	**Main Tasks**	**Main Tasks**
▸ Establishing medical device-related policies ▸ Establishing QMS Standards of Manufacturing site ▸ Processing and tracing management information on safety including adverse events	▸ Medical device review/evaluation ▸ Supporting innovative medical device approval ▸ Training technical document review agencies ▸ Implementing research on medical devices, Controls of reference materials	▸ QMS audit ▸ Issue of business license ▸ Post-market surveilance

MFDS collaborates with external third party organizations to increase efficiency and expertise in controlling medical devices.

Affiliated Organization

National Institute of Medical Device Safety Information (NIDS)	**A legal entity established in 2012** - Supports and provides with information regarding clinical trials, standards, safety, training, etc. - Issuses Notification of Class I devices & Certification of Class II devices

Related Organizations designated by MFDS

Medical Device QMS Audit Institutions	Conduct QMS audit and issuing certificates with MFDS (4 Institutions)
Medical Device Testing Laboratories	Test medical devices (15 Labs)
Technical Document Review Agencies	Review technical documents on class II devices (8 Agencies)
Medical Device Clinical Trial Centers	Hospitals designated by MFDS (166 Centers) Conduct clinical trials for medical devices
GLP Laboratories	Biological Evaluation of medical devics (5 Labs)

Establishment of Innovative Convergence Products Support Department

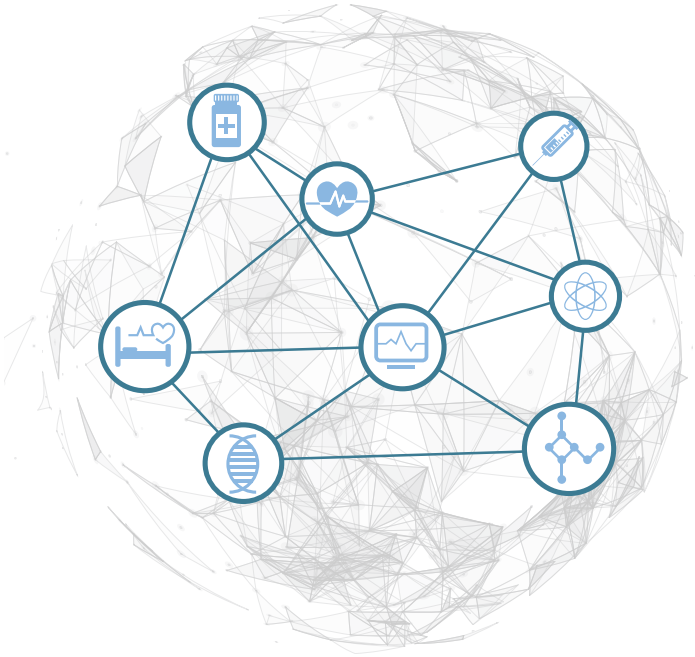
- Background: The need for the whole management of convergence products including innovative medical devices, advanced biopharamaceuticals, and regenerative medicines
- Organizational structure and its responsibilities

Convergence Technology Policy Team

- Building systems in support of convergence products
- Deciding whether the product is a convergence product
- Supporting capabilities of the reviewers

Approval Management Team

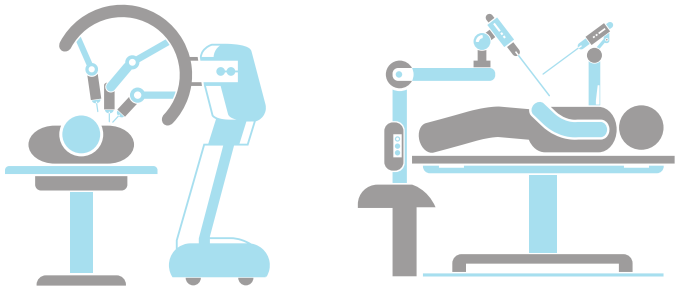
- Comprehensive reviews for medical products encom passing medical devices, medicines and biopharmaceuticals
- Consulting companies to commercialize medical products



04. Special New Acts on Innovative Medical Devices and IVDs

Legislation in support of innovative devices and promotion of the industry

1) Designating devices with cutting-edge technologies and even higher safety and effectiveness as innovative medical devices
2) Prioritizing the overall review over those of regular devices, and frequent checks for each stage of innovative devices
3) Designating companies that are proactively investing in R&D as an innovative devices companies and offering the first choice in bidding for government-funded projects

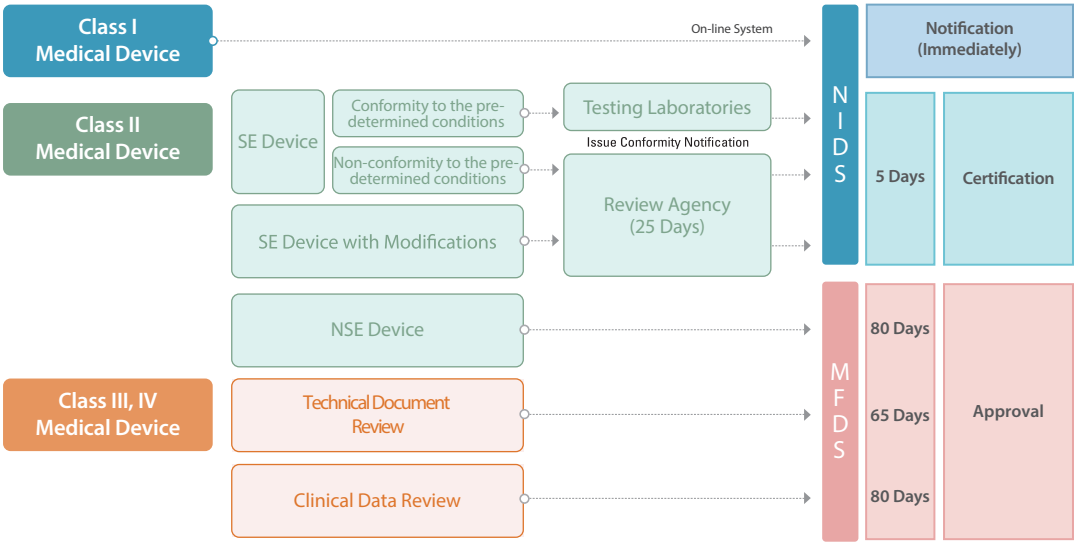


Legislation for In-Vitro Diagnostic (IVD) medical devices

1) Definitions and classifications of IVD devices
2) Simultaneous review of IVD devices and the corresponding drugs developed in conjunction with the IVD devices
3) Establishment of procedures to allow clinical tests only with approval of IRB

05. Predictable Approval System with Scientific Approach

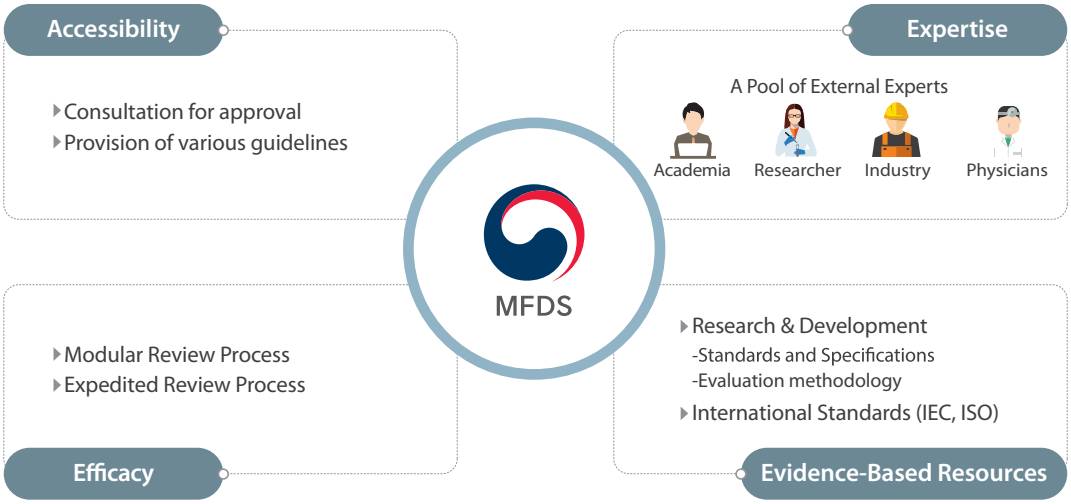
Based on risk classification of medical devices, each classes of devices have different pathways for a marketing authorization.



* Substantially Equivalent (SE), Not Substantially Equivalent (NSE)
* National Institute of Medical Device Safety Information

For an easy access and better compliance of regulations, MFDS provides consultations and various guidelines for applicants.

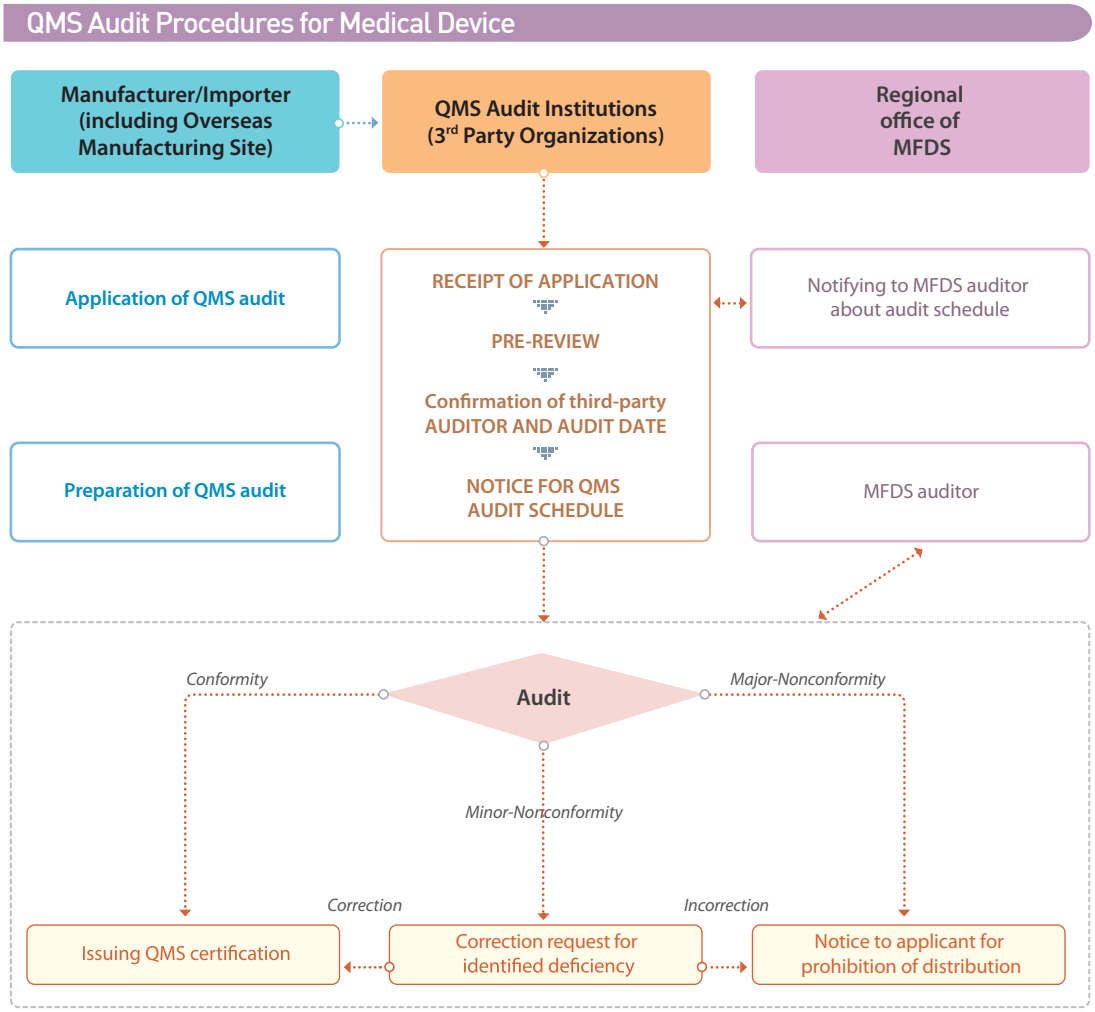
MFDS also gains additional scientific understanding from a pool of external experts as needed, and invests on various R&D projects to increase expertise in review and approval processes.



06. Emphasis on Quality: QMS

MFDS Quality Management System (QMS) regulations are made based on ISO 13485.

- All medical device manufacturers required to comply with QMS regulations if their devices are distributed in Korea
- On-site audits are mandatory for class 2, 3, and 4 devices manufacturers, but it is elective for class 1 device manufacturers



Types of Audits

- Initial audit : An initial audit to approve QMS conformity assurance
- Periodic audit : After the initial audit, at least one audit will be conducted within 3 years
- Audit of approval changes : Audits to be conducted if manufacturers notify the change of manufacturing sites
- Supplementary audit : Audits to be conducted if a product is added from a different product group

Method of Audit

- Conducting on-site audits and document review for each product group* of manufacturing sites

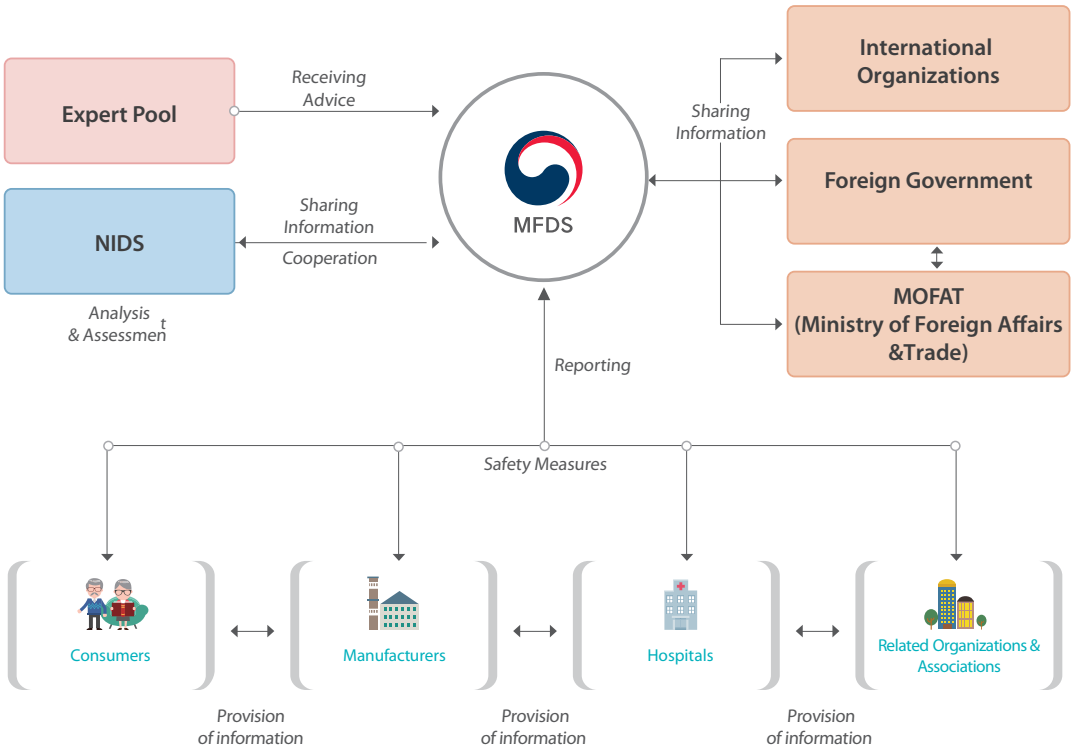
  * Product group : MFDS categorized the products into 26 product groups which use similar raw materials, manufacturing processes and QMS

07. Adverse Event Reporting

As a champion economy of APEC, Korea is putting a lot of effort into the harmonization of medical device vigilance in Asia Pacific region.

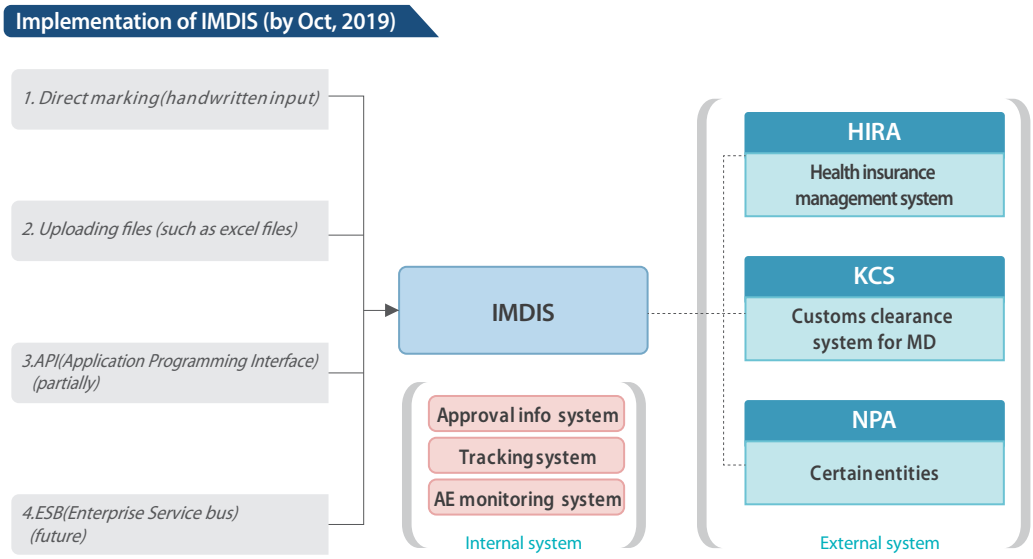
Medical device manufacturers, importers and distributors are required to report any adverse events and keep those records.

Medical Device Adverse Event Reporting and Management System

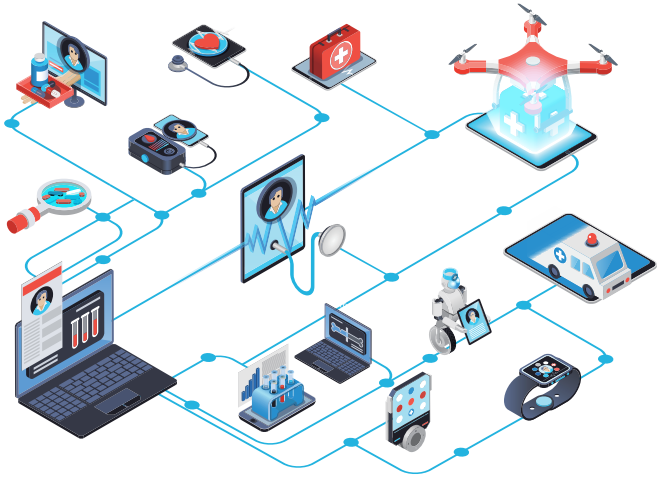


▸ All of collected information regarding adverse event reports are being reviewed and analyzed to be used for field safety

Integrated Medical Device Information System (IMDIS)



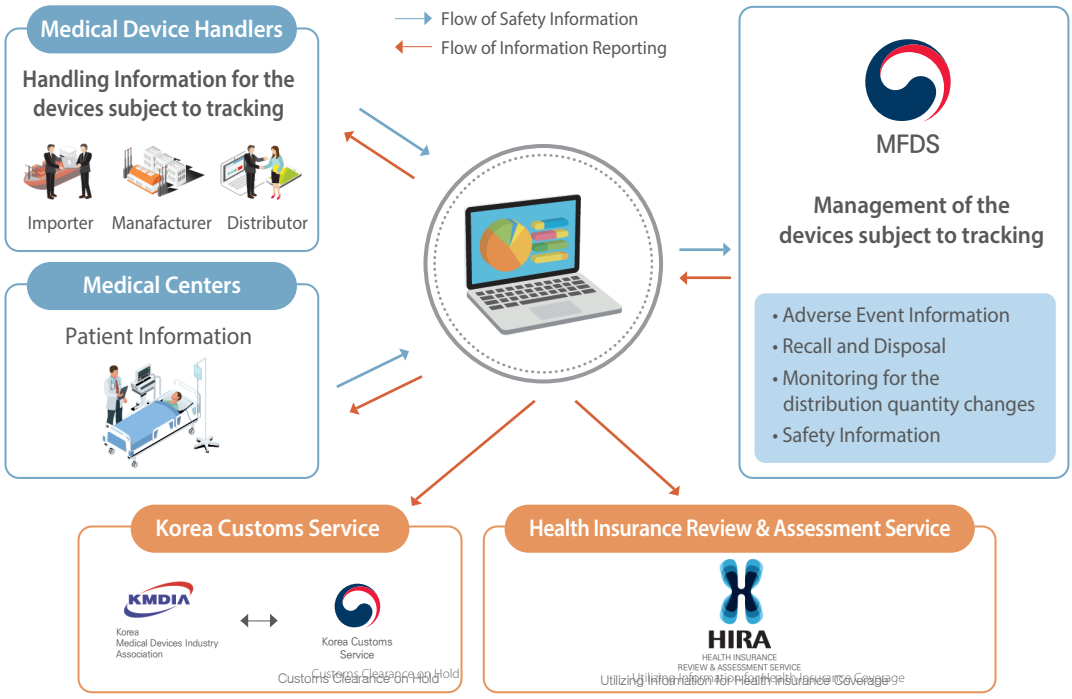
- An electronic data processing system to effectively record and manage information on medical devices from its approval through manufacturing, importing, distributing and the use
- To strengthen supply chain with prompt identification of defective medical devices and market withdrawals



08. Monitoring & Tracking System

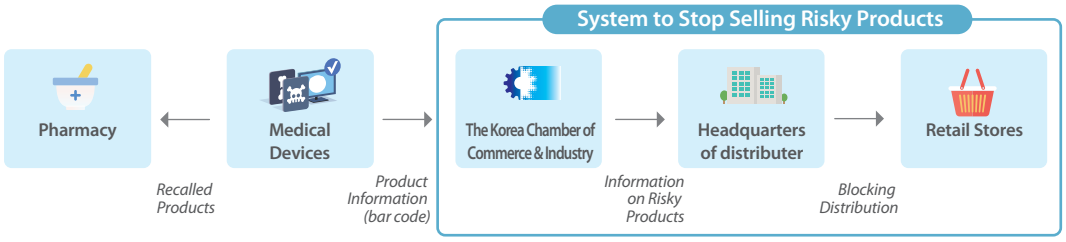
In order to keep track of patient safety information, MFDS designates 44 types of medical devices that are inserted in the human body for more than a year, or life-supporting devices that can be used in places other than medical institutions.

MFDS collects information about devices and patients from manufacturers and importers to assure the safe use of those devices and prevent medical incidents.



Revision and Reinforcement of Monitoring and Tracking Systems

- Creating a tracking system to identify the approval history, distribution channels, stock locations and the quantity of the product on the basis of the UDI system in case of problems on medical devices
- Creating an ability to halt the sale and distribution of products on the recall list



List of Medical Devices Subject to Tracking

1. Medical Devices that are inserted in the human body for one year or more

	Medical Devices	date
1	Pacemaker, cardiac, implantable	2004.07.28.
2	Pacemaker electrode cardiac, implantable	
3	Prosthesis, valve, cardiac, composite	
4	Prosthesis, valve, cardiac, biological	
5	Prosthesis, valve, cardiac, non-biological	
6	Defibrillator, implantable	
7	Infusion pump, electrically-powered, implantable	
8	Silicone gel-filled breast implants	2007.07.18.
9	Implantable defibrillator electode	2008.12.30.
10	Artificial temporomandibular prosthesis	2012.09.25.
⋮	⋮	⋮

2. Life-supporting medical devices that can be used in places other than medical institutions

	Medical Devices	date
1	low-powered defibrillator	2008.12.30
2	high-powered defibrillator	
3	Patient monitoring system (limited to the ones worn at all times.)	2012.09.25.
4	Prosthesis, valve, cardiac, non-biological	

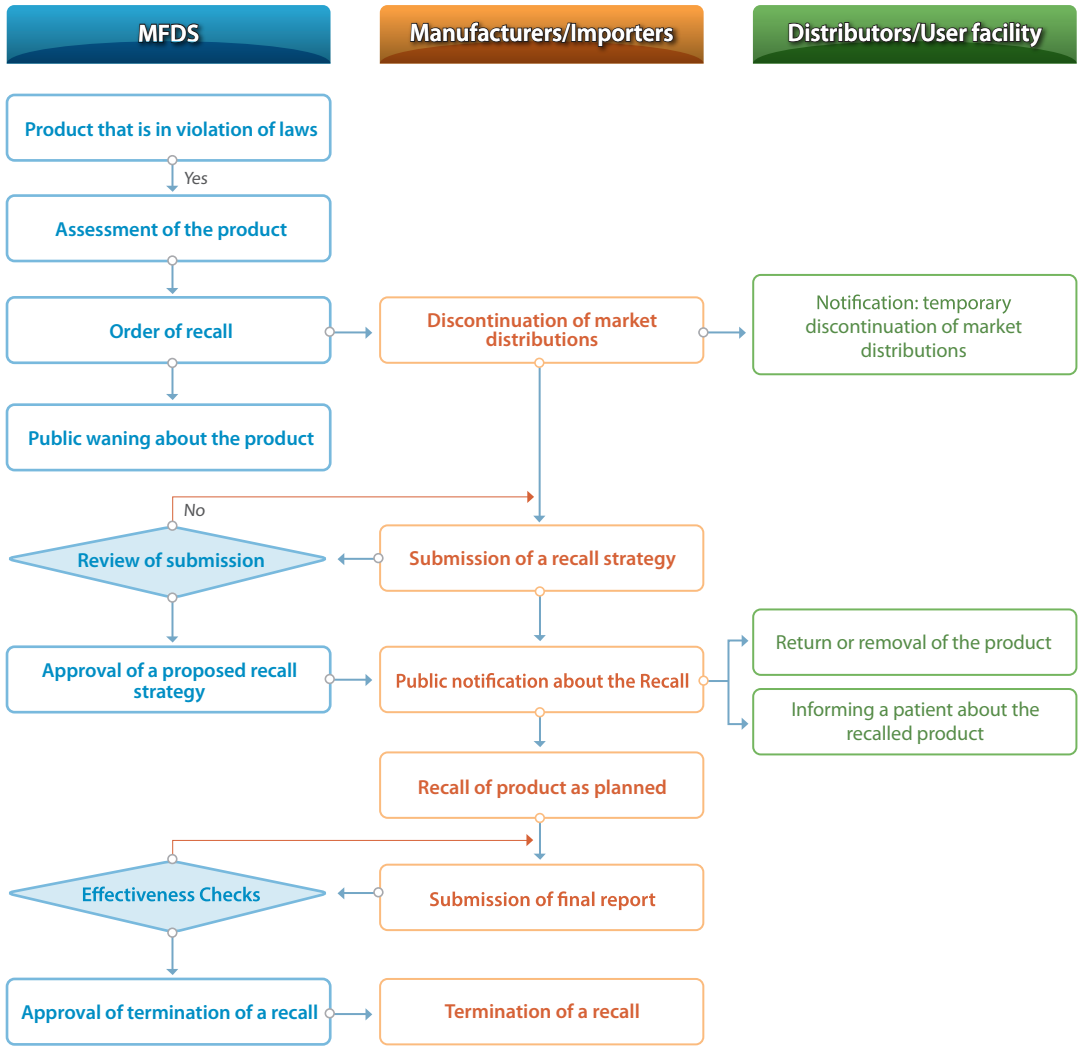
Detailed information of medical devices subject to tracking(52items) is posted on the website(www.mfds.go.kr/eng)

09. Recalls

Types of Recall

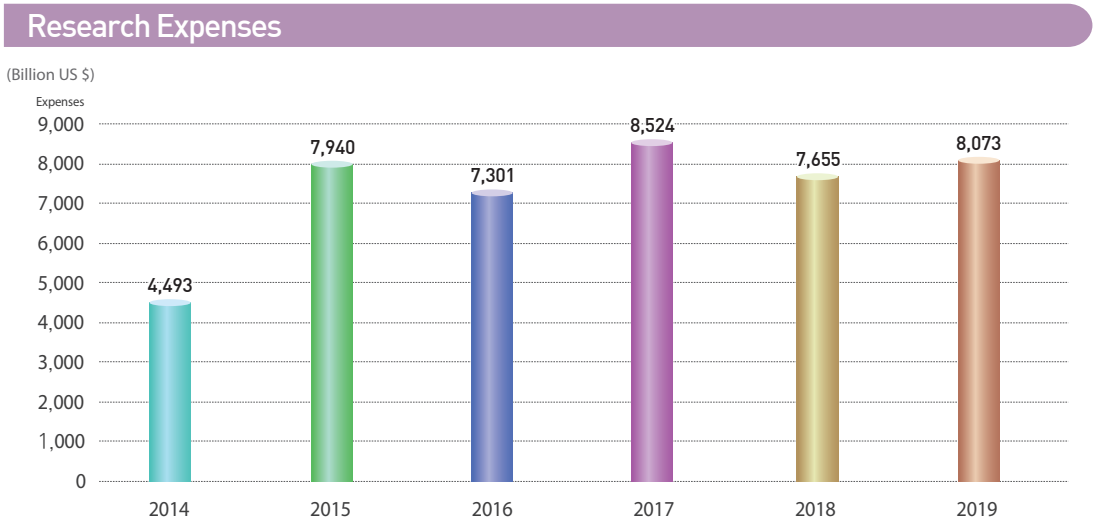
- (Firm-initiated Recall) Recall made usually voluntarily by the firm after the discovery of safety issues or product defects that may have potential health risk to patients.
- (Government-initiated Recall) Recall order made by Minister of MFDS when the product is determined to be defective or potentially harmful.

Procedure for Government-initiated Recall



10. Research Development Project Aimed at Advancing Medical Devices

Safety Control R&D on Medical Devices: 8.073 billion won.



Laying a cornerstone for scientific assessment in line with shifts in future medical environments, as well as with support for expedited commercialization and medical devices safety

- Research on setting a system and policies for pre and post-market safety anagement
- Creation of guidelines and development of tests for assessment of safety and efficiency of medical devices
- Development of preemptive assessment technologies in support of rapid commercialization of newly-developed convergence products
- Research on development of Korean standards (KS) and International standards regarding medical devices

Major Achievements in 2019

- Creating standards for assessment and management of Clinical Laboratory Authorization Certificate
- Completing the guideline for quality assessment of automatic hematology analyzer
- Creating and confirming reference materials for IVD devices
- Building standard data sets for each disease to ensure the performance and safety of CDSS medical devices
- Developing standards for smart healthcare convergence products

List of Reference Materials for IVD Devices

MFDS has steadily secured and distributed the reference standard of IVD for consistent quality.

- To secure quality reliability of the referece standards, MFDS has conducted the stability test on the reference standards in storage periodically

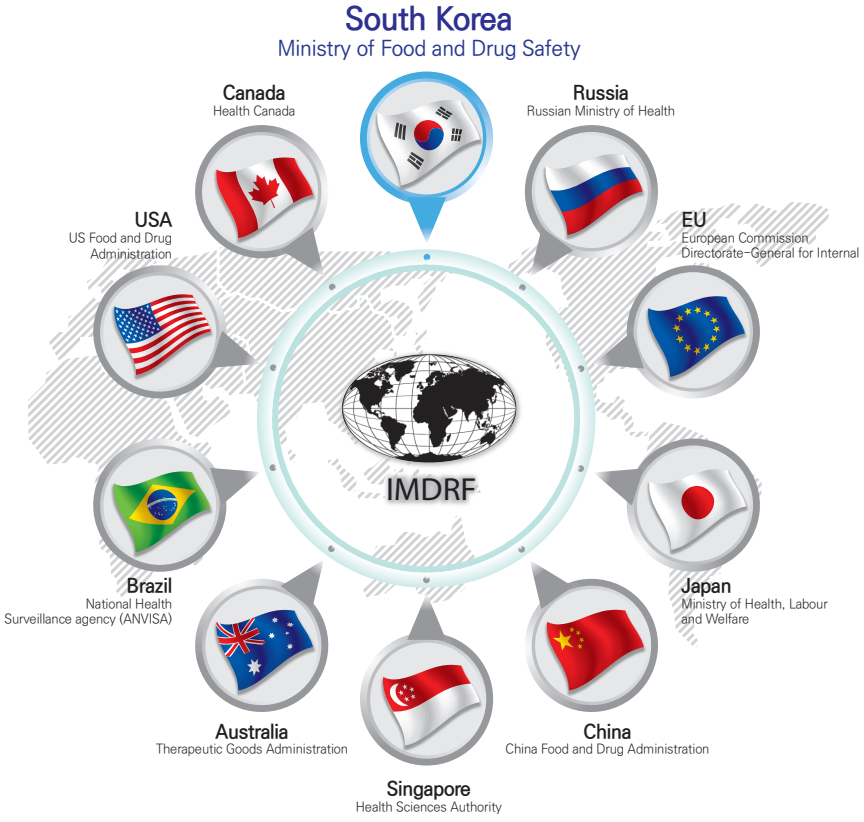
No	Cat. code	Item name
1	IVD-12/001	Rotavirus plasmid DNA (Mixed Panel)
2	IVD-12/002	Rotavirus RNA
3	IVD-12/003	Rotavirus Antigen (High/Medium/Low concentration)
4	IVD-12/004	Malaria antigen (Mixed titer performance panel)
5	IVD-12/005	Anti-Malaria (Mixed Titer Performance Panel)
6	IVD-12/006	Anti-Syphilis (Mixed Titer Performance Panel)
7	IVD-12/007	HIV-1 RNA (Working Standard)
8	IVD-12/008	HIV-1 DNA (rDNA-derived)
9	IVD-12/009	Group A Streptococcus DNA (High/Medium/Low concentration)
10	IVD-12/010	Group A Streptococcus Antigen (High/Medium/Low concentration)
11	IVD-12/011	Group B Streptococcus DNA (High/Medium/Low concentration)
12	IVD-12/012	Group B Streptococcus Antigen (High/Medium/Low concentration)
13	IVD-12/017	Anti-HAV (Working Standard)
14	IVD-12/018	Anti-HAV (Mixed Titer Performance Panel)
15	IVD-12/019	HBV DNA (Working Standard)
16	IVD-12/020	HBV DNA (rDNA-derived)
17	IVD-12/021	HCV RNA (Working Standard)
18	IVD-12/022	HCV DNA (rDNA-derived)
19	IVD-12/023	Streptococcus Pneumoniae Antigen (High/Medium/Low concentration)
20	IVD-12/024	Streptococcus Pneumoniae DNA (High/Medium/Low concentration)
21	03/010	Hepatitis B virus surface antigen
22	08/023	Human Papilloma Virus L1 DNA
23	08/024	Hepatitis B virus surface antigen (Working Standard)
24	08/029	ABO & D Frozen Red Blood Cell Panel
25	09/031	Anti-HIV 1 (Working Standard)
26	12/038	Anti-HIV 1 (Mixed Titer Performance Panel)
27	12/039	Anti-HIV 1 (Working Standard)
28	IVD-14/001	Hepatitis B virus surface antigen (Low titer performance panel)
29	IVD-14/002	Hepatitis B virus surface antigen (Mixed titer performance panel)
30	IVD-15/001	Anti-HIV 2 (Mixed Titer Performance Panel) (HIV-2/01~06)
31	IVD-15/002	Anti-HIV 2 (Mixed Titer Performance Panel) (HIV-2/07~12)

11. Sustainable Effort & Committment for International Cooperation

Joining of IMDRF as an Management Committee (MC) member and our participations in Work Items (WI)

- As of December, 2017, Korea officially joined IMDRF as a 10th MC member of International Medical Device Regulators Forum (IMDRF).
- In order to implement initiatives that are developed by IMDRF and successfully take part in IMDRF as an MC member, MFDS operates the domestic IMDRF steering committee which is composed of experts group from other regulatory authorities, industry, academia or research organizations.
  - MFDS is also actively participating in various work items of IMDRF including Medical Device Cybersecurity Guide, Medical Device Clinical Evaluation, Regulated Product Submission, Unique Device Identification, Standards, Adverse Event Terminology, Good Regulatory Review Practices, and Personalized Medical Devices.

Korea will assume the chairmanship of 2021 IMDRF



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